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REMARKS

In view of the following remarks, the Examiner is requested to allow Claims 1-9, 11-21 and 35-40, the only claims pending and under examination in this application.

Claims 1, 19-20, 35 and 37 have been amended. Claims 1 and 35 have been amended to incorporate the element of Claim 10. Consequently, Claim 10 has been cancelled. Claims 19 and 20 have been amended to correct their dependencies. Claim 37 has been amended to further exemplify the elements of the claim. Support for these amendments can be found throughout the specification and claims as originally filed. For instance, support may be found at original Claim 34. Accordingly, no new matter has been added.

As no new matter has been added by way of these amendments, entry thereof by the Examiner is respectfully requested.

Claims Objections

Claims 37-39 have been objected to by the Examiner. Claim 37 has been amended. Accordingly, in view of the amendment to Claim 37 this objection may be withdrawn.

Claims Rejections - 35 U.S.C. § 101

Claims 1 and 2 have been rejected under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory matter.

The Office asserts that Claims 1 and 2 are not direct to statutory subject matter. The Office alleges that the claimed methods do not produce a physical transformation or tangible result. The Applicants respectfully disagree. However, the Applicants have amended Claim 1 to more clearly set forth the elements of the claimed methods.

Claim 1, as amended, includes obtaining a sample form a subject and using that sample to determine a single nucleotide polymorphism profile. The single nucleotide polymorphism profile is then used to identify the source of the sample. The specification at page 12, lines 14 to 31 teaches various protocols that may be employed so as to determine the single nucleotide polymorphism profile. These protocols all involve a physical interaction. Accordingly, the Applicants contend that the rejected claims clearly produce a physical transformation and a tangible result.

In view of the above, the Applicants contend that the subject matter of Claims 1 and 2 is statutory and respectfully request that the 35 U.S.C. § 101 rejection be withdrawn.

Claim Rejections - 35 U.S.C. § 112, second paragraph

Claims 11-21 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 has been rejected. Claim 20 has been amended as suggested by the Examiner in order to overcome the rejection.

Claims 11-21 have been rejected because it is allegedly unclear what steps are involved in "determining an SNP profile." The Applicants respectfully disagree.

According to the M.P.E.P. § 2173.02: "The test for definiteness under 35 U.S.C. 112, second paragraph, is whether 'those skilled in the art would understand what is claimed when the claim is read in light of the specification.'"

Accordingly, the Applicants would like to draw the attention of the Office to the specification at page 12, lines 14-31, set forth below, wherein are disclosed representative embodiments of how an SNP profile may be determined.

"The SNP profile may be determined for a given sample using any convenient protocol. Representative protocols include both non array-based and array-based SNP detection protocols. As is known in the art, a number of methods are available for analyzing nucleic acids for the presence of a specific sequence, and particularly for the presence of a particular nucleotide base at a known SNP location of a particular sequence. Where large amounts of DNA are available, genomic DNA is used directly. Alternatively, the region of interest is cloned into a suitable vector and grown in sufficient quantity for analysis. The nucleic acid may be amplified by conventional techniques, such as the polymerase chain reaction (PCR), to provide sufficient amounts for analysis. The use of the polymerase chain reaction is described in Saiki et al. (1985) Science 230:1350-1354, and a review of current techniques may be found in Sambrook et al Molecular Cloning: A Laboratory Manual, CSH Press 1989, pp.14.2-14.33. Amplification may be used to determine whether a polymorphism is present, by using a primer that is specific for the polymorphism. Alternatively, various methods are known in the art that utilize oligonucleotide ligation as a means of detecting polymorphisms, for examples see Riley et al (1990) Nucleic Acids Res 18:2887-2890; and Delahunty et al (1996) Am J Hum Genet 58:1239-1246."

The specification from page 12, line 32 to page 14, line 30, further sets forth, in greater detail, additional techniques for determining an SNP profile.

Therefore, in view of the teachings of the specification, the Applicants contend that one of skill in the art would clearly understand what is meant by "determining an SNP profile." Consequently, the Applicants contend that the claims are clear and distinct and respectfully request that the 35 U.S.C. § 112, second paragraph, rejection of Claims 11-21 be withdrawn.

Claim Rejections - 35 U.S.C. § 102

Claims 1, 3-21 and 35-40 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hogan et al. (US Patent Application 09/976,423).

According to the MPEP, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. See MPEP 2131.

Claim 1 is directed to a method of identifying a source of a genomic nucleic acid sample. Claim 1 as amended includes the steps of obtaining a sample from a subject, determining a single nucleotide polymorphism (SNP) profile for the sample, identifying the source of the sample from the determined SNP profile, and assaying the sample for the presence of at least one analyte if the identified SNP profile matches a predetermined source. Accordingly, an element of the claims is assaying a sample for the presence of at least one analyte if the identified SNP profile matches a predetermined source.

The Office asserts that Hogan anticipates the claims because Hogan discloses a method for performing a perioperative genomic screening of a subject (paragraph 113) and using the results of the perioperative genomic screening for archiving and tracking data specific to the subject. However, the Applicants respectfully disagree.

The Applicants contend that Hogan does not disclose using a genomic profile to determine if the identified SNP profile matches a predetermined source, much less assaying a sample from the subject for the presence of at least one analyte. Hogan does not disclose this element because the genomic profile disclosed in Hogan is **either** used to initially screen a sample for a given polymorphism that is indicative of a subject's risk of anesthesia related complications **or** it is used to track genetic data specific to the subject. However, at no point does Hogan disclose generating a SNP profile to determine the source of the sample and if the SNP profile matches a predetermined source then assaying the sample for an analyte.

In view of the above, Hogan is deficient in that it fails to teach all the elements of the rejected claims, namely, assaying a sample for the presence of at least one analyte if the identified SNP profile matches a predetermined source. Accordingly, because Hogan does not teach every element of the rejected claims it fails to anticipate the presently claimed invention. Consequently, the Applicants respectfully request that the 35 U.S.C. § 102(b) rejection of Claims 1, 3-21 and 35-40 be withdrawn.

Claim Rejections - 35 U.S.C. § 103(a)

Claim 2 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hogan et al. in view of Hunter et al. (US Patent Application 09/822,635)

According to the MPEP § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Claim 2 is dependent on Claim 1. Claim 1 has been amended. An element of Claim 1, as amended, is assaying a sample for the presence of at least one analyte if the identified SNP profile matches a predetermined source. As described above, Hogan is deficient in that it fails to teach or suggest this element. As Hunter was cited solely for disclosing a method for evaluating a subject by comparing the subject's "expression" profile to a reference profile, Hunter fails to remedy the deficiencies of Hogan. Therefore, the combination of Hogan in view of Hunter fails to teach every element of Claim 2. For this reason alone this rejection may be withdrawn.

Additionally, the Office acknowledges that Hogan does not teach comparing an SNP profile to a reference profile. The Office, therefore, relies upon Hunter to remedy the deficiencies of Hogan. However, Hunter does not teach comparing SNP profiles, rather Hunter discloses:

> [0357] In yet another aspect, the invention features a method of evaluating a test compound (see also, "Screening Assays", above). The method includes providing a cell and a test compound; contacting the test compound to the cell; obtaining a subject expression profile for the contacted cell; and comparing the subject expression profile to one or more reference profiles. The profiles include a value representing the level of 16836 expression. In a preferred embodiment, the subject expression profile is compared to a target profile, e.g., a profile for a normal cell or for desired condition of a cell. The test compound is evaluated favorably if the subject expression profile is more similar to the target profile than an expression profile obtained from an uncontacted cell.

As can be seen with reference to the above excerpt, Hunter is simply concerned with finding a drug that modulates the expression levels of the 16836 nucleic acid molecule. Hunter compares the cellular expression profile of a cell that has been contacted with a test compound to a reference profile (e.g., from a normal cell) to determine if the cell in the presence of the test compound evidences an expression profile that is similar to the reference profile (e.g., of the normal cell). Accordingly, Hunter does not compare SNP profiles. Therefore, the combination of Hogan in view of Hunter fails to teach every element of Claim 2. For this reason alone this rejection may be withdrawn.

Accordingly, in view of the above, a *prima facie* case of obviousness has not been established because the cited references fail to teach every element of Claim 2. Consequently, the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claim 2 be withdrawn.

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CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Mike Beck at (408) 553-3864.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10021287-1.

Respectfully submitted,

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